

C. REMARKS

This is an amendment filed in conjunction with a request for continued examination of the above-identified application.

Claims 1-7 have been cancelled without prejudice and Claims 8-22 have been added. The fact that Claims 1-7 have been cancelled without prejudice is not to be construed as an admission by Applicants or Applicants' attorneys that such claims are not patentable, and Applicants reserve the right to prosecute such claims in a continuing application.

The present invention is directed to a method of producing purified human papillomavirus (HPV) virus-like particles (VLPs) comprising purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains the recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP. The expressed HPV L1 protein or truncated version thereof then is assembled into purified human papillomavirus virus-like particles (VLPs).

The Examiner had rejected the claims under 35 U.S.C. 112, second paragraph, in that the claims omitted essential steps.

The Examiner is reminded that all that is required by 35 U.S.C. 112, second paragraph, is that the claims point out particularly and claim distinctly the subject matter sought to be patented. (See In Re Borkowski, 164 U.S. P.Q. 642 (C.C.P.A. 1970), at 645.) Applicants and only Applicants are the first to have purified a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains the recombinantly expressed HPV L1 protein or truncated version thereof in a form which is not a VLP, and assembled the expressed HPV L1 protein or truncated version thereof into purified papillomavirus virus-like particles.

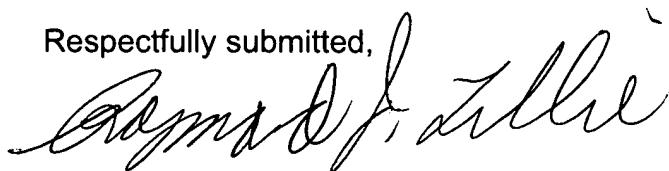
It is clear that Applicants are claiming a method of producing purified human papillomavirus particles by purifying a recombinantly expressed HPV L1 protein or a truncated version thereof in the presence of at least one reducing agent that maintains the expressed protein or truncated version thereof in a form which is not a VLP, and then assembling the purified HPV L1 protein or truncated version thereof into virus-like

parties. Applicants have not indicated that they intend the claims to be of a different scope. Thus, the claims point out particularly and claim distinctly the subject matter that Applicants regard as the invention. (*Id.*, at 645 – 646.)

As in Borkowski, the Examiner cannot study Applicants' disclosure, and then determine whether Applicants' claims are broader than the Examiner's conception of what "the invention" is. (See Borkowski, supra, at 645.) Section 112 does not permit such an approach to claims. *Id.*

In sum, Applicants have pointed out particularly and claimed distinctly the subject matter that they regard as the invention. It is not within the prerogative of the Examiner to conclude or hold that additional steps in the claim are required for compliance with 35 U.S.C. 112, second paragraph. In that the claims particularly point out and claim distinctly the subject matter Applicants regard as the invention, the claims are patentable under 35 U.S.C. 112, second paragraph. For the above reasons and others, this application is in condition for allowance and a favorable action is hereby solicited.

Respectfully submitted,



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